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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,017	03/23/2004	David Feygin	115-001US	4800
22897 DEMONT & B	7590 10/01/2007 REYER LLC		EXAMINER	
100 COMMON	IS WAY, Ste. 250		MUSSELMAN, TIMOTHY A	
HOLMDEL, NJ 07733			ART UNIT	PAPER NUMBER
·			3714	
•			MAIL DATE	DELIVERY MODE
			10/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/807,017	FEYGIN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Timothy Musselman	3714				
The MAILING DATE of this communication app. Period for Reply	ears on the cover sheet with the	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailling date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATIO 16(a). In no event, however, may a reply be ting till apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. mely filed  n the mailing date of this communication. ED (35 U.S.C. § 133).				
Status ·						
1) Responsive to communication(s) filed on						
,_	• •					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims		, ,				
4) Claim(s) 1-38 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) 1,4-6,8,11-13,19,21-27,30,31 and 34-38 is/are rejected.						
7) Claim(s) 2,3,7,9,10,14-18,20,28,29,32 and 33 i						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examine	r.					
10) $\boxtimes$ The drawing(s) filed on <u>23 March 2004</u> is/are: a) $\boxtimes$ accepted or b) $\square$ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:	priority under 35 U.S.C. § 119(a	a)-(d) or (f).				
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)						
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/04,6/05.	5) Notice of Informal 6) Other:	Patent Application				

#### **DETAILED ACTION**

# Specification

The specification is objected to because the first paragraph (related applications) appears to be an empty form paragraph with blank entry fields that were most likely left in the specification as an oversight.

Removal or correction to an appropriate form is required.

## Claim Rejections - 35 USC § 102

The following is a quotation of the relevant portion of 35 U.S.C. 102 that forms the basis for the rejections made in this section of the office action;

(e) the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent.

Claims 32-33 are rejected under 102(e) as being anticipated by Nicholls et al. (US 6,773,263).

Regarding claims 1 and 4, Nicholls discloses an apparatus comprising a palpation module disposed beneath a pseudo skin wherein the palpation module comprises a vein. See col. 2: 9-24.

Regarding claim 5, Nicholls further discloses wherein the pseudo vein yields to applied pressure and moves downward. See col. 3: 35-49, and note that this limitation is disclosed because the faithful replication of the particular anatomy disclosed would include this feature.

Regarding claims 6 and 30, Nicholls further discloses wherein the pseudo vein contains a certain amount of rigidity. See col. 3: 35-40.

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Regarding claims 8 and 38, Nicholls discloses wherein the pseudo vein is contained within the outer skin (i.e. not visible), and wherein the pseudo vein can be palpated (i.e. felt). See col. 2: 9-24.

Regarding claims 11-13, 27, and 31, Nicholls discloses wherein the vein generates a force that opposes downward motion of the pseudo vein. See col. 3: 21-49. Note that the opposing force is natural, because the vein is not suspended in free space, and thus any downward force would produce a constant counter force that varies with the applied pressure.

Regarding claims 21-23 and 34-37, Nicholls discloses an apparatus comprising a rigid housing with an opening. See fig. 1, label 20. Nicholls further discloses a palpation module disposed within the housing that comprises a vein, and wherein the housing is covered with a pseudo skin that obscures the vein from view. See col. 2: 9-24.

Regarding claim 26, Nicholls further discloses an electronics module interfaced to the palpation module. See col. 3: 7-24.

# Claim Rejections - 35 USC § 103

The following is a quotation of the relevant portion of 35 U.S.C. 103 that forms the basis for the rejections made in this section of the office action;

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Claims 19 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls et al. (US 6,773,263) in view of Cunningham et al. (US 6,470,302).

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Regarding claims 19 and 24, Nicholls discloses all of the features of parent claim 1 as described above, but fails to teach of a skin stretch module disposed beneath the pseudo skin, wherein the amount the user stretches the skin is measured. However, Cunningham teaches of a vascular access simulator which includes this feature. See col. 10: 47 - col. 11: 10. It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize this feature in the system of Nicholls, so as to expand the invention to include vascular access features to become a more versatile trainer.

Regarding claim 25, Nicholls discloses a simulated circulatory system complete with simulated blood flow (see col. 3: 35-40), but fails to teach wherein the system is used for vascular access training, including the insertion of a catheter or needle. However, Cunningham discloses a similar system that teaches of vascular access training. See col. 5: 10-17. The combination of these systems would have been obvious to one of ordinary skill in the art at the time of the invention, because vascular access simulations are known in the art as taught by Cunningham, and combining these features with the system of Nicholls would have produced no unexpected results.

## Allowable Subject Matter

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 2 is allowable over the prior art, because although the prior art teaches of palpation modules comprising veins disposed beneath a simulated skin, there is no teaching wherein the palpation module measures changes in the position of the vein.

Claims 3 and 7 are objected to as being dependent upon rejected parent claims, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 3 and 7 are allowable over the prior art because there is no teaching wherein the palpation module is capable of varying a stiffness of the pseudo vein.

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Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 9 is allowable over the prior art because although there are teachings of vein palpation modules, there is no teaching wherein the vein can be felt or not felt as desired.

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 10 is allowable over the prior art because although there are teachings of vein palpation modules, there is no teaching wherein the vein cannot be felt if the user applies a sufficient amount of pressure.

Claims 14 and 28-29 are objected to as being dependent upon rejected parent claims, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims are allowable over the prior art, because although the prior art teaches of forces opposing vein motion (natural physical opposing forces), there is no teaching wherein this force is a controllable magnetic force.

Claims 15-17 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 17 and 20 are allowable over the prior art at least because they depend from allowable intervening claims.

Claim 18 is objected to as being dependent upon rejected parent claims, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 18 is allowable over the prior art, because although the prior art teaches of measuring pressure in a simulation of an occlusion procedure (Eggert, US 6,443,735, col 5: 10-20), there is no teaching wherein the vein movement is used as an indicator that an occlusion technique has been performed.

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Claims 32 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims are allowable over the prior art because the prior art does not teach of measuring the position of the vein by disposing the vein on a movable first plate, and measuring the distance between said first plate and a second plate as the vein (and hence the first plate) is moved.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy Musselman whose telephone number is (571)272-1814. The examiner can normally be reached on Mon-Thu 6:00AM - 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-

1000.

TM

Ronald Laneau

Supervisory Primary Examiner

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